

Petitioner Sandoz Canada Inc. (“Sandoz”) respectfully submits this memorandum of law in support of its application for an order, pursuant to 28 U.S.C. § 1782 and Rules 26, 30, and 45 of the Federal Rules of Civil Procedure, granting Sandoz leave to serve the annexed subpoena, attached hereto as Exhibit 6, on Ronald Vladyka, a resident of Somerset, New Jersey, such that Sandoz can utilize the documents and deposition testimony sought in foreign proceedings.

I. JURISDICTION

This Court may properly exercise subject matter jurisdiction pursuant to 28 U.S.C. §1331 and 28 U.S.C. §1782.

Venue is proper in this District pursuant to 28 U.S.C. §1391.

II. BACKGROUND

A. The Canadian Patent Litigation Between Roche and Sandoz

Hoffmann-La Roche Limited and InterMune, Inc. (collectively, “Roche”) filed several patent litigation actions against Sandoz in the Federal Court of Canada (Court File Nos.: T-704-19, T-705-19, and T-708-19) (the “Canadian patent litigation”), alleging infringement of Canadian Patent Nos. 2,620,380, entitled “Capsule formulation of pirfenidone and pharmaceutically acceptable excipients” (the “’380 Patent”), and 2,762,013, entitled “Granulation of pirfenidone and pharmaceutically acceptable excipients” (the “’013 Patent”) (collectively, the “Patents in Issue” (attached as Exs. 1 and 2)). Sandoz served Statements of Defence in the same proceedings on the basis, *inter alia*, that: (1) the asserted claims of the Patents in Issue are invalid; and (2) the Sandoz proposed product would not infringe the asserted claims of the Patents in Issue.

Each of the Patents in Issue name three inventors: Ronald Vladyka, Ramachandran Radhakrishnan, and Kenneth Sultzbaugh. Roche agreed to make Ramachandran Radhakrishnan and Kenneth Sultzbaugh available for examination for discovery, and those

individuals have been deposed. To date, however, Ronald Vladyka, who no longer works for Roche, has not agreed to produce documents or attend a deposition. Upon information and belief, as an inventor of the Patents in Issue, Ronald Vladyka has highly relevant information in his possession that pertains to claims in the Canadian patent litigation that is non-duplicative of the other inventors.

The trial for the proceedings for the Patents in Issue is scheduled to commence on January 11, 2021 in Toronto, Ontario, Canada. There is a scheduling order in these proceedings which requires Sandoz to serve its expert reports on validity by August 10, 2020. The information sought to be obtained by Sandoz from Ronald Vladyka relates to his role in the development of the subject-matter claimed in the Patents in Issue, which may be relevant to the patent validity issues under the laws of Canada.

B. The Federal Court of Canada Issued a Commission and Letter of Request for the Requested Discovery

Upon application by Sandoz, the Federal Court of Canada issued a Commission and Letter of Request to this Court on November 25, 2019 (attached as Exs. 3-5), based upon Ronald Vladyka's residence in Somerset, New Jersey. (Ex. 4 at 5). Specifically, the Order from the Federal Court of Canada found:

(a) the motion is made *bona fide*; (b) the issues for which the evidence is sought are issues which the Court will need to determine; (c) the witnesses sought to be examined are inventors of the patents in issue and may have evidence material to the issues; (d) the named inventors sought to be examined reside in the United States and are not currently employees of the Plaintiffs; they cannot be compelled to be examined in Canada and have not agreed to be examined in Canada; (e) procedures are available to compel the named inventors to be examined in the United States; and (f) there is a reasonable probability the order will be complied with under the laws of the United States

(Ex. 3 at 2-3). The issued Letter of Request seeks limited documents from Ronald Vladyka, including: (1) his curriculum vitae; (2) copies of any affidavits or declarations that have been

sworn by Ronald Vladyka in any matter relating to the subject-matter of the '380 and '013 Patents, or corresponding foreign patents and applications, including United States Patent Nos. 7,767,225, 7,988,994, 8,383,150, 8,753,679, Publication No. US 2014/242159, European Patent No. EP 1,940,364 and Application EP 2,431,025; and (3) copies of documents (including laboratory notebook pages, notes, memoranda, reports, data, correspondence, emails, computer files, and notes of any discussions) relating to the pirfenidone formulations and clinical studies described in the '380 and '013 Patents. (Ex. 4 at 5-6).

The Letter of Request further seeks a deposition of Ronald Vladyka before the Commissioner for a period of one day in or near Somerset, New Jersey in a place mutually determined by the parties or as determined by this Court. (*Id.* at 6-7). The Letter of Request seeks Ronald Vladyka to answer questions on the areas set out below as related to the '380 and '013 Patents:

- a. background and experience, including pharmaceutical formulation and clinical trials;
- b. preparation of pirfenidone formulations containing a binder;
- c. administration of pirfenidone formulations containing a binder in humans, and collection and analysis of pharmacokinetic parameters;
- d. use of pirfenidone for treating idiopathic pulmonary fibrosis;
- e. administration of capsules of pirfenidone comprising no excipients in humans, and collection and analysis of pharmacokinetic parameters;
- f. physical and chemical characterization of any interaction between pirfenidone and excipients;
- g. study on the impact of the interaction between pirfenidone and excipients, if any, on pharmacokinetic parameters.

(*Id.*)

Sandoz requested through counsel for Roche that Ronald Vladyka voluntarily agree to attend a deposition after the Commission and Letter of Request issued; however, Sandoz was

informed that Ronald Vladyka has not agreed to provide discovery, forcing Sandoz to file this Application for the requested discovery. The discovery requested in the annexed subpoena matches the discovery requested in the Letter of Request. Sandoz seeks the requested discovery by no later than May 15, 2020, so that the discovery may be considered in connection with the expert reports on validity due on August 10, 2020.

III. ARGUMENT

Section 1782 of Title 28 of the United States Code permits the United States District Courts to grant discovery for use in a foreign proceeding. The statute, in relevant part, states:

The district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal The order may be made pursuant to a letter rogatory issued, or request made, by a foreign or international tribunal or upon the application of any interested person and may direct that the testimony or statement be given, or the document or other thing be produced, before a person appointed by the court. By virtue of his appointment, the person appointed has power to administer any necessary oath and take the testimony or statement. The order may prescribe the practice and procedure, which may be in whole or part the practice and procedure of the foreign country or the international tribunal, for taking the testimony or statement or producing the document or other thing.

28 U.S.C. § 1782(a). Under the express terms of the statute, a person seeking discovery under §1782 must establish that (1) the person from whom discovery is sought is resides or is found in the judicial district in which the §1782 application is made; (2) the discovery is for use in a proceeding before a foreign or international tribunal; and (3) the person seeking discovery is an interested person. *Id.*; see also *In re Bayer AG*, 146 F.3d 188, 193 (3d Cir. 1988).

When a court finds that the statutory requirements of 28 U.S.C. § 1782 are met, it may, in its discretion, grant an application for discovery. *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 264 (2004). The United States Supreme Court has articulated four factors relevant to a Court's discretionary determination under §1782:

- (1) whether “the person from whom discovery is sought is a participant in the foreign proceeding,” and thus “the need for § 1782(a) aid generally is not as apparent as it ordinarily is when evidence is sought from a nonparticipant in the matter arising abroad;”
- (2) “the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance;”
- (3) “whether the §1782(a) request conceals an attempt to circumvent foreign proof gathering restrictions or other policies of a foreign country or the United States;”
- (4) whether the request is “unduly intrusive or burdensome.”

Id. at 264-266. “A court should apply these factors in support of §1782’s ‘twin aims’ of ‘providing efficient assistance to participants in international litigation and encouraging foreign countries by example to provide similar assistance to our courts.’” *In re Biomet Orthopaedics Switz. GmbH*, 742 Fed. Appx. 690, 696 (3d Cir. 2018) (quoting *Intel*, 542 U.S. at 252); *see also Lancaster Factoring Co. v. Mangone*, 90 F.3d 38, 41 (2d Cir. 1996) (“In pursuit of these twin goals, the section has, over the years, been given increasingly broad applicability.”) (internal quotations and citations omitted).

A. Sandoz Satisfies the Statutory Requirements of 28 U.S.C. § 1782

There can be little dispute that Sandoz’s application satisfies the three statutory requirements of §1782.

First, Ronald Vladyka resides, and is currently employed, in Somerset, New Jersey, which is within this Court’s jurisdiction. (Ex. 4 at 5).

Second, the discovery sought is for use in a currently pending Canadian patent litigation before the Federal Court of Canada. (Ex. 3).

Third, Sandoz is an “interested person” because it is the defendant in the Canadian patent litigation. *Intel Corp.*, 542 U.S. at 256 (“No doubt litigants are included among, and may be the most common example of, the ‘interested person[s]’ who may invoke §1782”). Additionally, as discussed above, the Federal Court of Canada issued a Letter of Request for

the requested discovery to this Court, which separately satisfies the third requirement of §1782.

B. The Court Should Exercise its Discretion to Grant the Requested Discovery Order

As described below, Sandoz’s Application should be granted because all four *Intel* factors weigh in favor of issuing the subpoena attached as Exhibit 6.

First, where, as here, discovery is sought from an individual who is not participating in the foreign proceedings, and who is outside the reach of the foreign tribunal, the need for court-ordered discovery is apparent. As the Supreme Court explained, “[a] foreign tribunal has jurisdiction over those appearing before it, and can itself order them to produce evidence. In contrast, nonparticipants in the foreign proceedings may be outside the foreign tribunal’s jurisdictional reach; hence, their evidence, available in the United States, may be unobtainable absent §1782(a) aid.” *Intel Corp.*, 542 U.S. at 264 (internal citations omitted). Ronald Vladyka is not a party to the Canadian patent proceedings, and, as a resident of this District, is outside the jurisdictional reach of the Federal Court of Canada. Sandoz requested through counsel for Roche that Ronald Vladyka voluntarily produce documents and appear for a deposition—before and after the Letter of Request issued from the Federal Court of Canada—but, Sandoz has been informed that he has not agreed to provide discovery, rendering the discovery unobtainable absent §1782 aid from this Court. Thus, this factor weighs in favor of issuing the subpoena.

The second factor—the nature of the foreign proceedings and the receptivity of the foreign tribunal to federal-court judicial assistance—requires courts to consider whether the United States’ assistance would offend the foreign country, and whether the material sought is admissible in the foreign tribunal. *In re O’Keeffe*, 646 F. Appx 263, 266-67 (3d Cir. 2016). A party moving to quash a subpoena based on this element “must present authoritative proof that the foreign court would reject the evidence obtained with the aid of Section 1782.” *Id.*

Here, the Order issuing the Letter of Request and Commission demonstrates that the foreign tribunal is receptive to—and affirmatively seeks—an order from this Court granting the requested discovery. Ex 3; *see also In re Digital Shape Techs., Inc.*, 2016 U.S. Dist. LEXIS 94885, at *8 (N.D. Cal. July 20, 2016) (“The Canadian court’s order authorizing issuance of the subpoena demonstrates that the request is not an attempt to circumvent proof-gathering restrictions in either Canada or the United States, and that the Canadian court would be receptive to an order from this Court.”). Thus, this factor weighs in favor of issuing the subpoena.

The third factor also suggests that discovery should be granted, as this application is not an attempt to circumvent any foreign proof-gathering restrictions. Again, the issuance of the Letter of Request and Commission from the Federal Court of Canada demonstrates that the subpoena is not an attempt to circumvent any foreign proof gathering restrictions. *See* Ex. 3. Thus, this factor weighs in favor of issuing the subpoena.

Finally, this application does not contain unduly burdensome requests. The documents and deposition testimony sought in the Letter of Request and affixed subpoena are narrowly tailored to the facts at issue in the Canadian patent proceedings concerning Ronald Vladyka’s role as an inventor of the Patents in Issue. Thus, this factor weighs in favor of issuing the subpoena.

IV. CONCLUSION

Sandoz respectfully requests that its Application under 28 U.S.C. §1782 be granted, and that the Court enter an Order, pursuant to 28 U.S.C. §1782 and Rules 26, 30, and 45 of the Federal Rules of Civil Procedure, granting Sandoz leave to serve Ronald Vladyka with the subpoena attached hereto as Exhibit 6.

Respectfully Submitted,

Dated: March 5, 2020

By: Brian Prew

Brian Prew
GREENBERG TRAUIG, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
Tel: (212) 801-3129
Email: prewb@gtlaw.com

Of Counsel

Jonathan D. Ball, Ph.D.
Jeffrey R. Colin
GREENBERG TRAUIG, LLP
MetLife Building
200 Park Avenue
New York, NY 10166
Tel: (212) 801-2223
Email: ballj@gtlaw.com
Email: colinj@gtlaw.com

Attorneys for Sandoz Canada Inc.